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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 09/445,653 | 07/17/2000 | Alexander V. Kabanov | UNMC-63117B | 1205 |
| 110 | 7590 | 04/09/2004 | EXAMINER | |
| DANN, DORFMAN, HERRELL & SKILLMAN | | | WEBMAN, EDWARD J | |
| 1601 MARKET STREET | | | ART UNIT | PAPER NUMBER |
| SUITE 2400 | | | 1617 | |
| PHILADELPHIA, PA 19103-2307 | | | | |

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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09/448653

[REDACTED]

EXAMINER

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| ART UNIT | PAPER NUMBER |
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3/18/08

DATE MAILED:

This is a communication from the examiner in charge of your application.

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OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 11/24/03

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 5 - 26 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) 12-14, 20-26 is/are allowed.
 Claim(s) 5-11, 15-19 is/are rejected.
 Claim(s) _____ is/are objected to.
 Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Applicants have dropped the limitation regarding crosslinking. Thus, the 103 rejection is reinstated over claims 5-11, 15-19. See amendment filed 4/11/03.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-11, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US Patent No. 5,410,016) in view of Ahmad et al. (US Patent No. 5,112,611), and Nakayama et al. (U.S. Patent No. 5,531,917) and Weiner et al. (U.S. Patent No. 5, 171,737).

Hubbell et al. Teach block copolymers comprising a water-soluble region such as polylactic or polyamino acid (column 7, line 6 to column 8, line 68).

Controlled drug delivery of active agents such as enzymes from devices such as microspheres is disclosed (column 10, lines 29-48).

Hubbell et al. do not teach a charged surfactant.

Ahmad et al. teach papain for aiding human digestion (abstract).

Controlled release is disclosed (column 3, lines 7-11).

Nakayama et al. teach the stabilization of a proteolytic enzyme with a surfactant (abstract). Combinations of nonionic, anionic, and amphoteric surfactants are specified (column 2, line 62 bridging column 3, line 12). Papain is disclosed (column 3, lines 17-18). Sodium lauroyl sarcosinate and lauryl dimethylaminoacetic betaine are specified (column 5 and 6, Table 1).

Weiner et al. teach dioleoyl phosphatidylethanolamine (DOPE) and dioleoyl phosphatidylcholine (DOPC) as surfactants used for delivery of bioactive agents (abstract, column 2, lines 28-34).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to deliver papain with the device of Hubbell et al to achieve the beneficial effect of aiding human digestion in view of Ahmad et al. and to add surfactants to achieve the beneficial effect of stabilizing the enzyme in view of Nakayama et al.

As to the claimed complex, it is argued that such is inherently formed during mixing of the components to make the obvious composition. As to the particular claimed polyanionic and polycationic segments of the claimed block copolymer, polyaspartic acid and polylysine are well known in the art as commercially available polyamino acids for the Hubbell et al. biodegradable region.

As to the claimed nonionic surfactants, one of ordinary skill would use DOPE or DOPC as such because of their utility for delivering bioactive agents in view of Wiener et al.

As to the claims weight percent, it is within the skill in the art to select optimal parameters such as ratios or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Therefore, the ratios or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

March 22, 2004

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 170